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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/073,705 | 02/11/2002 | Dean Hughes | HO-P02368US0 | 4397 |
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| FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095 | | | EXAMINER RAMANA, ANURADHA | |
| | | | ART UNIT 3732 | PAPER NUMBER |

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,705

Applicant(s)

HUGHES ET AL.

Examiner

Anu Ramana

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 22, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application. Applicant's submission filed on June 22, 2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 10-15 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 10, line 12, it is unclear which surface "the bearing surface" is, i.e., is it on the prosthesis body or on "another prosthesis portion." Further, in line 13, it is unclear which non-load bearing surface the Applicant is referring to, i.e., is it the non-load bearing surface "on the prosthesis body" or the non-load bearing surface on "another prosthesis portion." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afriat et al. (US 6,203,576) in view of Davidson (US 5,180,394).

Regarding claims 1-17 and 19-20, Afriat et al. disclose a knee joint prosthesis having a femoral component 1 with two condylar portions (5a, 5a), a cam 9 extending between the

Art Unit: 3732

posterior portions of the condylar portions, a tibial component 2 configured to be implanted into a patient's tibia, and a tibial insert 3, made of an organic polymer such as high-density or "ultra-high molecular weight" polyethylene, having a proximal surface shaped to articulate against femoral component 1 wherein the distal surface of tibial insert 3 fits against the proximal surface of tibial component 2 and a central projecting rib or post 30 on the tibial insert 3 engages intercondylar cage or box 8 of femoral component 1 for posterior stabilization (Figure 1, col. 4, lines 19-67 and col. 5, lines 4-9 and lines 16-19).

Afriat et al. disclose the claimed invention except for a diffusion-hardened surface or coating on a portion of the cam or the condylar portions of the femoral component.

Davidson teaches diffusion-bonded or "diffusion-hardened" coating of articulating surfaces (including load bearing and non-load bearing surfaces) of implants such as a knee joint prosthesis with blue-black or black zirconium oxide to minimize wear and improve the fatigue properties of the implant (col. 1, lines 14-35 and lines 61-68; col. 2, lines 1-8; col. 5, lines 11-26 and lines 47-55; col. 6, lines 51-68; and col. 7, lines 1-11 and lines 36-48). Davidson further teaches coatings of variable thickness (col. 8, lines 7-9 and lines 22-40; and col. 10, lines 18-21).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a diffusion-hardened coating on load-bearing and non load bearing contact surfaces of the knee joint prosthesis or implant of Afriat et al., as taught by Davidson, to minimize wear, reduce friction and improve fatigue properties of the implant.

Further, regarding claims 5 and 13, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the prosthesis of the combination of Afriat et al. as modified by Davidson with a thicker coating on a load bearing surface (greater wear) than a non load bearing surface (lesser wear), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burstein et al. (US 4,298,992) in view of Davidson (US 5,180,394).

Art Unit: 3732

Burstein et al. disclose a knee joint prosthesis having a femoral component with two condylar portions (10,12), a cam or horizontal bar 16a extending between the posterior portions of the condylar portions and a tibial insert 30 configured to be implanted into a patient's tibia having a proximal surface shaped to articulate against femoral component when post 42 on the tibial insert engages the intercondylar recess or cage 16 of the femoral component wherein the tibial insert is made of a low wearing plastic (Figures 1-3 and 5-6, col. 3, lines 20-73 and col. 4, lines 1-29).

Burstein et al. disclose the claimed invention except for a diffusion-hardened surface or coating on a portion of the cam or the condylar portions of the femoral component or other load-bearing and non-load bearing surfaces.

Davidson teaches diffusion-bonded or "diffusion-hardened" coating of articulating surfaces (including load bearing and non-load bearing surfaces) of implants such as a knee joint prosthesis with blue-black or black zirconium oxide to minimize wear and improve the fatigue properties of the implant (col. 1, lines 14-35 and lines 61-68; col. 2, lines 1-8; col. 5, lines 11-26 and lines 47-55; col. 6, lines 51-68; and col. 7, lines 1-11 and lines 36-48).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a diffusion-hardened coating on a contact surface (i.e., cam surface or the surface of the condylar portions of the femoral component) of the knee joint prosthesis or implant of Burstein et al., as taught by Davidson, to minimize wear and improve the fatigue properties of the implant.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afriat et al. (US 6,203,576) and Davidson (US 5,180,394), as applied to claims 1, 10 and 16, further in view of Walker (US 3,837,009).

The combination of Afriat et al. and Davidson discloses all elements of the claimed invention except for polished articulating surfaces.

Walker teaches high polishing of interengaging or "articulating" surfaces of a knee prosthesis to reduce friction to minimize wear and prolong the life of the knee prosthesis (col. 4, lines 17-23).

Art Unit: 3732

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided highly polished articulating surfaces in the prosthesis of the combination of Afriat et al. and Davidson, as taught by Walker, to minimize wear and prolong the life of the knee prosthesis.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burstein et al. (US 4,298,992) in view of Davidson (US 5,180,394), as applied to claims 10 and 16, further in view of Walker (US 3,837,009).

The combination of Burstein et al. and Davidson discloses all elements of the claimed invention except for polished articulating surfaces.

Walker teaches high polishing of interengaging or "articulating" surfaces of a knee prosthesis to reduce friction to minimize wear and prolong the life of the knee prosthesis (col. 4, lines 17-23).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided highly polished articulating surfaces in the prosthesis of the combination of Burstein et al. and Davidson, as taught by Walker, to minimize wear and prolong the life of the knee prosthesis.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3732

Claims 1-17 and 19-20 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 of copending application 10/185,386 (US 2004/0002766 or '2766 herein) in view of Afriat et al. (US 6,203,576) and Davidson (US 5,180,394). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Claims 1-3 of '2766 disclose all elements of the claimed invention except for a tibial insert, a pair of generally parallel vertical walls connected to the inner sides of the posterior condylar portions and a wear resistant coating on articulating surfaces.

Afriat et al. and Davidson supply the missing elements.

Claims 10-20 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 of copending application 10/185,386 (US 2004/0002766 or '2766 herein) in view of Burstein et al. (US 4,298,992) and Davidson (US 5,180,394). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Claims 1-3 of '2766 disclose all elements of the claimed invention except for a femoral component having two condylar portions with a cam extending between the posterior of the condylar portions, the cam shaped as a horizontal bar with a diffusion hardened surface along a portion of its length.

Burstein et al. and Davidson supply the missing elements.

Claims 10-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20 and 26 of U. S. Patent No. 6,447,550 ('550 herein) in view of Davidson (US 5,180,394).

Although the conflicting claims are not identical, they are not patentably distinct from each other because, claims 20 and 26 of '550 have all the elements of the claimed invention except for a diffusion hardened coating on load bearing and non-load bearing surfaces.

Davidson teaches a diffusion-hardened coating on articulating surfaces (including load bearing and non-load bearing surfaces) of a knee prosthesis to minimize wear and improve the fatigue properties of the implant.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a diffusion-hardened coating on articulating surfaces,

Art Unit: 3732

including load bearing and non-load bearing surfaces, in the '550 prosthesis, as taught by Davidson, to minimize wear and improve the fatigue properties of the implant.

Claims 14-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20 and 26 of U. S. Patent No. 6,447,550 ('550 herein) and Davidson (US 5,180,394), as applied to claim 10, in view of Burstein et al. (US 4,298,992).

Although the conflicting claims are not identical, they are not patentably distinct from each other because, the combination of the claims 20 and 26 of '550 and Davidson discloses all the elements of the claimed invention except for the structural elements of a prosthesis body having two condylar portions with a cam extending between the condylar portions and a tibial insert with a post to engage the prosthesis body.

Burstein et al. supply the missing structural elements.

Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20 and 26 of U. S. Patent No. 6,447,550 ('550 herein) in view of Davidson (US 5,180,394), as applied to claim 10, further in view of Walker (US 3,837,009).

Although the conflicting claims are not identical, they are not patentably distinct from each other because, claims 20 and 26 of '550 have all the elements of the claimed invention except high polishing of the articulating surfaces of the knee prosthesis.

Walker teaches high polishing of interengaging or "articulating" surfaces of a knee prosthesis to reduce friction to minimize wear and prolong the life of the knee prosthesis (col. 4, lines 17-23).

Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20 and 26 of U. S. Patent No. 6,447,550 ('550 herein) and Davidson (US 5,180,394) in view of Burstein et al. (US 4,298,992), as applied to claim 16, further in view of Walker (US 3,837,009).

Art Unit: 3732

Although the conflicting claims are not identical, they are not patentably distinct from each other because, the combination of claims 20 and 26 of '550 and Davidson and Burstein et al., have all the elements of the claimed invention except high polishing of the articulating surfaces of the knee prosthesis.

Walker teaches high polishing of interengaging or "articulating" surfaces of a knee prosthesis to reduce friction to minimize wear and prolong the life of the knee prosthesis (col. 4, lines 17-23).

Response to Arguments

Applicant's arguments filed on June 22, 2004, under "REMARKS," have been fully considered but are not persuasive with respect to claims 1-20.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In the instant case, Davidson teaches coating of articulating surfaces of a joint prosthesis with blue-black or black zirconium oxide (col. 5, lines 11-26). It is the Examiner's position that articulating surfaces of a prosthesis inherently include both load bearing surfaces and non-load bearing surfaces or a combination thereof. The horizontal cam extending between the intercondylar portions of a knee prosthesis is but one example of a surface articulating against another surface in a joint prosthesis. Thus, Davidson provides the necessary motivation to provide a coating of blue-black or black zirconium oxide on the articulating surfaces of a knee prosthesis, such as the Afriat et al. prosthesis.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so

Art Unit: 3732

long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anuradha Ramana*
August 18, 2004

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